



Food and Drug Administration
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August 11, 2014

Cutera Incorporated
Bradley Renton, Ph.D.
Vice President, Regulatory and Medical Affairs
Quality Assurance and Compliance Officer
3240 Bayshore Boulevard
Brisbane, California 94005

Re: K133945
Trade/Device Name: enlighten Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general
and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 18, 2014
Received: July 23, 2014

Dear Dr. Renton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K133945

Device Name

enlighten Laser System

Indications for Use (Describe)

The enlighten laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

532 nm

The 532 nm wavelength of the enlighten laser system is indicated for the treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III.

1064 nm

The 1064 nm wavelength of the enlighten laser system is indicated for the treatment of benign pigmented lesions on patients with all skin types (Fitzpatrick I-VI).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Neil R Ogden -S

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Section 5 510(K) Summary

This 510(K) Summary of safety and effectiveness for the enlighten laser system is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Cutera, Inc.
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Contact Person:	Bradley Renton
Telephone:	415-657-5568 – phone
Fax:	415-715-3568 – fax
Email:	brenton@cutera.com
Preparation Date:	August 7, 2014
Device Trade Name:	enlighten Laser System
Common Name:	Dermatology Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878.4810
Legally Marketed Predicate Devices:	Cutera Q-Switch Laser System (K102954) Quanta System Q-Plus T (K073549) Cynosure PicoSure (K121346)
Device Description:	<p>The enlighten laser system is a multi-wavelength, pulsed laser system designed for the treatment of benign pigmented lesions. A key feature of the device is its ability to produce multiple laser wavelengths (1064 nm and 532 nm) and pulse widths (750 ps and 2 ns, nominal). The laser, power supplies and control electronics are housed inside a console equipped with a touchscreen control panel. The laser treatment parameters are selected using the control panel. Laser emission is activated by depressing a footswitch. The system is operated using 110 V mains AC power.</p> <p>An articulated arm with rotational mirror knuckles delivers the laser beam from a laser head inside the console to a handpiece. The handpiece is equipped with a detachable tip that determines the spot size of the laser beam on the treatment surface. Multiple tips are provided to vary the spot size as desired for treatment. The beam of a low-power red diode laser is also transmitted through the arm to provide an aiming beam.</p>

Attachment 5 510(K) Summary

Intended Use: The enlighten laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

Specific Indications: **532 nm**

The 532 nm wavelength of the enlighten laser system is indicated for the treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III.

1064 nm

The 1064 nm wavelength of the enlighten laser system is indicated for the treatment of benign pigmented lesions on patients with all skin types (Fitzpatrick I-VI).

Performance Data: IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety

IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility

Nova Software Verification and Validation Testing Report (V0083 r1)

Results of Clinical Study: Two IRB-approved prospective clinical studies were conducted to assess the safety and efficacy of the enlighten laser system for the treatment of benign pigmented lesions using the picosecond output of the system.

532 nm

Twenty subjects with Fitzpatrick skin types I-III diagnosed with benign pigmented lesions of the hand (lentigines, ephelides and/or seborrheic keratosis) were enrolled and received up to two picosecond 532-nm treatments performed 6 weeks apart. Standardized photographs were taken at baseline and 12 weeks following the final treatment. Blinded assessment of improvement (clearing) in pigmented lesions was completed by two independent dermatologists. Pain levels during treatment and adverse events were recorded during all visits and via phone surveys. Patients were followed to 24 weeks post final treatment for safety assessment.

Based on blinded photographic assessments of the 20 subjects, treatments indicated a clinically and statistically significant median improvement of 1.50 (one-sample Wilcoxon signed rank test, 95% CI: 1.25 – 2.00, P=0.000). The reviewers were highly consistent and accurate (kappa of 1, P=0.000) in identification of the before and after photographs (all 20 randomized before and after photos were correctly identified by both reviewers). Based on subject

Attachment 5 510(K) Summary

questionnaires, 95% of subjects reported that they were “satisfied” and “very satisfied” with the improvement (clearing) in benign pigmented lesions at 12 weeks post final treatment.

All subjects tolerated treatments well (median pain score of 1.4 (0-10)). As expected, subjects experienced erythema (redness), edema (swelling) followed by crusting/scabbing. Blisters were observed in 3 (15%) subjects. About half of the subjects (65%) had purpura (bruising). All adverse effects resolved without intervention. No serious adverse events were noted. No questionable, pre-cancerous or malignant lesions were observed during the 24-week follow-up period.

1064 nm

Twenty three subjects with Fitzpatrick skin types II-VI diagnosed with benign pigmented lesions (lentigines, ephelides, dermatosis papulosa nigra and/or seborrheic keratosis) of the face, body or hands were enrolled and received one picosecond 1064-nm treatment. Standardized photographs were taken at baseline and 6 weeks following the final treatment. Blinded assessment of improvement (clearing) in pigmented lesions was completed by two independent dermatologists. Pain levels during treatment and adverse events were recorded during all visits and via phone surveys. Patients were followed to 12 weeks post final treatment for safety assessment.

Blinded reviewers' photographic assessments of benign pigmented lesion improvement at 6 weeks post treatment for the 23 subject treatment areas revealed a clinically and statistically significant median improvement score of 0.75 (one-sample Wilcoxon signed rank test, 95% CI: 0.25 – 1.0, $p=0.001$). The mean improvement score was 0.6. Based on subject questionnaires, 91% of subjects expressed satisfaction with lesion clearance at 6 weeks following laser treatment.

All subjects tolerated treatments well (mean pain score of 2.5 ± 1.3 [1-5]). As expected, all subjects experienced erythema (redness) and edema (swelling). Mild crusting/scabbing was observed in 14 (61%) subjects. All adverse effects resolved without intervention. No serious adverse events were noted. No questionable, pre-cancerous or malignant lesions were observed during the 12-week follow-up period.

Histology

Biopsy samples were obtained on a volunteer basis from two subjects enrolled in the clinical studies for 1064-nm and 532-nm laser treatment immediately post and 6-months post treatment respectively. The histologic sections of the biopsy samples were stained with hematoxylin and eosin (H&E) prior to microscopic examination. Slides for two histologic sections for each biopsy were

Attachment 5 510(K) Summary

sent to an independent, board-certified dermatologist for evaluation. The immediate post treatment histology showed multiple 20-40 micron diameter vacuoles near the dermal epidermal junction. In most cases, these vacuoles were noted just superficial to the junction and extend into the mid epidermis. There also appeared to be some mild changes in the superficial cutaneous vasculature, where small areas of vacuolar changes were noted near the walls of the 10-20 micron diameter vessels. No gross extravasation of RBCs was observed. In the 6-month histology, other than the absence of basilar layer hyperpigmentation, there were no obvious findings that would indicate the skin was treated. That is, the vasculature, dermis, and epidermis all show normal architecture.

The treatment outcomes and histology observed in this study for 532-nm and 1064-nm treatment agree with the results of published studies with nanosecond QS lasers, which had the same mechanism of action and tissue interaction as the study device and have a proven baseline efficacy.

Treatment of benign epidermal pigmented lesions with the enlighten laser system was found to be safe and effective, with minimal discomfort and adverse effects, allowing the conclusion that the enlighten laser system is substantially equivalent to the predicate devices for the requested indications.

Summary of
Technological
Characteristics:

See table below

Conclusion:

The enlighten laser system is comparable to the predicate devices in terms of indications for use, technical specifications, operating performance features and general design.

Section 5
510(K) Summary

	enlighten Laser System	Cutera Q-Switch Laser System (K102954)	Quanta System Q-Plus T (K073549)	Cynosure PicoSure (K121346)
Wavelength	1064 nm Nd:YAG laser 532 nm Nd:YAG laser	1064 nm Nd:YAG laser 532 nm Nd:YAG laser	1064 nm Nd:YAG laser 532 nm Nd:YAG laser	755 nm Alexandrite laser
Max Pulse Energy	1064 nm: 600 mJ 532 nm: 300 mJ	1064 nm: 1600 mJ 532 nm: 500 mJ	1064 nm: 1000 mJ 532 nm: 500 mJ	200 mJ
Max Fluence	1064 nm: 10 J/cm ² 532 nm: 2.5 J/cm ²	1064 nm: 12 J/cm ² 532 nm: 5 J/cm ²	1064 nm: 22 J/cm ² 532 nm: 11 J/cm ²	6.37 J/cm ²
Pulse Duration (nominal)	750 ps or 2 ns	5-20 ns	6 ns	≤ 900 ps
Spot Size	2, 3, 4, 6 or 8 mm	2-8 mm	Up to 6 mm	Zoom 2-6 mm; fixed 2, 3, 4, 6, 8 or 10 mm
Output Mode	Pulsed	Pulsed	Pulsed	Pulsed
Repetition Rate	≤ 10 Hz or single shot	≤ 10 Hz or single shot	≤ 10 Hz or single shot	≤ 10 Hz or single shot
Laser Media	Q-switched Nd:YAG laser	Q-switched Nd:YAG laser	Q-switched Nd:YAG laser	Q-switched Alexandrite laser
User Interface	Push-button control or LCD color touchscreen	Push-button control or LCD color touchscreen	Push-button control or LCD color touchscreen	Push-button control or LCD color touchscreen
Treatment Beam Activation	Footswitch	Footswitch	Footswitch	Footswitch
Delivery System	Articulated arm with user-detachable handpiece tips	Articulated arm with user-detachable handpiece tips	Articulated arm with user-detachable handpiece tips	Articulated arm with user-detachable handpiece tips
Aiming Beam	635 nm	635-655 nm	635 nm	630-690 nm
Handpiece Tips (How Supplied)	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable